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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/816,784

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Paul J. Thompson

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08/21/2008

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EXAMINER

GANESAN, SUBA

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

08/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/816,784

Applicant(s)

THOMPSON ET AL.

Examiner

SUBA GANESAN

Art Unit

3774

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-22,24-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-22,24-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 4/11/2008 have been fully considered but they are not persuasive. Applicant argues that Phelps does not disclose end struts being radially thinned along their lengths relative to the main body. Examiner disagrees, since the flared ends of the Phelps stent depicted in fig. 11 flare radially outwardly while tapering; the ends have radial thinning along their lengths relative to the main body.
2. Applicant argues that Shanley only teaches the use of ductile hinges to accommodate mechanical strain during radial expansion and compression. Examiner does not find this persuasive, since one of ordinary skill in the art would understand that a bend location includes stress strain forces during expansion that would benefit from the ductile hinges as taught by Shanley (for example by providing a reliable location of deformation). Applicant argues that neither Shanley nor Phelps discloses or teaches reduced radial wall thickness. However, the rejection is based upon a combination of Shanley and Phelps, one of ordinary skill in the art, taking the two disclosures as a whole, would understand that the notches be placed at the location of desired bending, that is, resulting in an area of reduced radial wall thickness. Applicant argues that combining Shanley and Phelps would cause prolapse and restenosis. Examiner disagrees, prolapse and restenosis are of primary concern in any stent design, the optimal degree of stent-to vessel coverage can still be obtained while combining the teachings of Shanley with Phelps.

3. Regarding claim 30, the claim only requires a stent between "vessels". Examiner submits that the left ventricle and coronary artery are both vessels.
4. With respect to Bonsignore, the referee does not teach away from combination with Shanley since the bridges would be the location of bending and thus would benefit from reduced cross section without changing the principle operation of Bonsignore.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

2. Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Phelps et al. (U.S. Pat. No. 6,290,728).
3. Phelps discloses a stent comprising a main body defining a plurality of cells with a plurality of end struts 30, the end struts being thinned along their lengths relative to the main body (see fig. 11).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-3, 5-17, 25-26, 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phelps et al. (U.S. Pat. No. 6,290,728) in view of Shanley (U.S. Pat. No. 6,241,762).
2. Phelps et al. discloses a stent comprising a main body with a plurality of cells and flared ends with predefined bend locations. The end structure includes a plurality of cantilever members connected at the bend location (see for example fig. 8). Phelps further discloses a stent implanted at the junction between two vessels, with the main body located within the first vessel and the end structure conformed to an interior surface of the second vessel (fig. 8). The stent of Phelps is delivered via a delivery catheter (146) and is implanted at the junction of two vessels (fig. 8).
3. However, Phelps does not disclose the use of notches to facilitate bending. Shanley teaches the use of notches for the purpose of bending sections of a stent. These notch sections have a reduced cross sectional area (see fig. 8 and Abstract) which appear to be 25-60% smaller than adjacent locations (see hinge 90, fig. 4b), and are located on both the interior and exterior surfaces of the stent (see fig. 3a, 4b). Shanley further teaches the use of shoulders at the bend locations (see fig 4b, noting that notch sides 96 define shoulders of struts 88) and linking members that extend between the struts (see fig. 10 noting that a linking member connects adjacent struts 72 via notches 74). The examiner is considering the areas of reduced cross sectional areas of Shanley to be reduced in a radial direction relative to the central longitudinal axis of the stent. Therefore it would have been obvious to one of ordinary skill in the art to modify the bend locations of Phelps to include notches, shoulders, and linking members

as taught by Shanley for the purpose of facilitating improved bending and reducing strain at the bend location to eliminate the risk of breaking. Although the notches of Shanley appear to be about 25-60% smaller than adjacent sections, Shanley appears not to specifically disclose this. However, it would have been obvious to one of ordinary skill in the art to include a reduced cross sectional area that is 25-60% smaller than adjacent locations for the purpose of defining a specific bend limit (col. 9 line 6-17).

4. Claims 18-22, 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonsignore et al. (U.S. P.G. Pub. No.: 2004/0186555) in view of Shanley (U.S. Pat. No. 6,241,762).

5. Bonsignore et al discloses a stent comprising a main body with a plurality of cells and flared ends with predefined bend locations (see fig. 7). X-ray visible marker 804 is positioned within enlargement 802 of the flared cantilever member. Bonsignore et al. discloses a stent with support members defining an undulating pattern of peaks and valleys extending about a circumference with end struts flared relative to the main body, the end struts being connected to at least some peaks of the main body (see fig. 7). Bonsignore does not disclose the use of notches to facilitate bending. Shanley teaches the use of notches for the purpose of bending sections of a sent. Therefore it would have been obvious to one of ordinary skill in the art to modify the bend locations of Bonsignore to include notches, shoulders, and linking members as taught by Shanley for the purpose of facilitating improved bending and reducing strain at the bend location to eliminate the risk of breaking.

6. Regarding claims 20,21, Bosignore fails to disclose end struts connected to every peak or every third peak. It would have further been obvious to one of ordinary skill in the art to modify the stent of Bosignore to include connecting an end strut to every peak or every third peak of the end support member for the purpose of increasing the amount of anchoring and support structures at the implantation site and/or modifying the flexibility of the entire stent body.

7. With respect to claim 22, Bosignore fails to disclose end struts with two enlargements with radiopaque markers for each end strut. It would have been further obvious to one of ordinary skill in the art to modify the stent of Bosignore to include two enlargements including radiopaque markers for the purpose of increasing the visibility of the stent about its entire circumference.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. G./
Examiner, Art Unit 3774

/William H. Matthews/
Primary Examiner, Art Unit 3774